



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/076,488 | 02/19/2002 | Ichiro Takai | 0020-4958P-SP | 9923 |

2292 7590 07/31/2003
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

| |
|----------|
| EXAMINER |
|----------|

KIM, SUN U

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1723

DATE MAILED: 07/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|----------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/076,488 | TAKAI, ICHIRO |
| | Examiner John Kim | Art Unit 1723 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 19 February 2002 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1723

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite for failing to particularly point a structure such as a control unit for determining a pressure of a blood flow line on the basis of a pressure of the dialysate detected by the pressure-detecting means at the time of temporary stop of ultrafiltration caused by the temporarily stopping operation of the ultrafiltration unit. As presently recited in claim 1, such structure is not positively claimed but written in steps or an intended use of the apparatus. Claims 2-3 and 5 also do not positively claim a structural element, but these claims recite steps or functions. Claim 4 depends on the rejected claim 1.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3-4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,487,827 (hereinafter referred to as Peterson et al). Peterson et al teach a dialyzer, a dialysate pressure transducer (64) (see figure 1A), an ultrafiltration unit (142-149, 516) (see figure 1B) and a display means for displaying arterial and venous blood pressure (see figure 8) (see col. 6, lines 32-34; col. 8, lines 28-41; col. 14, lines 16-33; col. 16, line 1 – col. 18, line 31; col. 21, lines 13-27)(claims 1, 3-4). Recitation of “said system is adapted to determine a pressure of a blood flow line on the basis of a pressure of the dialysate detected by the pressure-detecting

means at the time of temporary stop of ultrafiltration caused by the temporarily stopping operation of the ultrafiltration unit" is an intended use of the apparatus. Regarding claim 6, Peterson et al teach that dialysate flow is bypassed i.e. No ultrafiltration state and pressure of dialysate and inherently blood pressure are detected (see col. 25, line 34 – col. 26, line 41; col. 14, lines 18-33).

5. Claims 2 and 5 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,580,460 and 4,021,341 and 4,680,122 and 4,762,618 teach ultrafiltration unit in dialysis apparatus. U.S. Patent No. 6,077,443 teaches method for monitoring a vascular access during a dialysis treatment.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 872-9311, and the fax phone number for all other official faxes is (703) 872-9310.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

John Kim
John Kim
Primary Examiner
Art Unit 1723

J. Kim
July 24, 2003